

Appl. No. 09/529,575  
Response Dated Oct. 12, 2004  
Reply to Office Action of Jul. 12, 2004

### REMARKS

Claims 31, 32, 36, 41-46, and 48-53 are pending in the present application and stand rejected.

### REJECTIONS UNDER 35 USC § 103(a)

Claims 31, 32, 36, 41-46, and 48-53 stand rejected under 35 USC § 103(a) as being unpatentable U.S. Patent 5874164 to Caldwell (hereinafter "Caldwell"). With respect to claims 31, 32, and 36, the Office contends that Caldwell discloses all aspects of the claimed invention but remains silent as to the percent by weight of the protease inhibitor. Caldwell discloses an absorbent article at least a portion of which comprises a protease inhibitor which is pentamidine. Therefore, the Office asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to have the protease inhibitor present in the article in a range of about 0.0001% to about 30% by weight. The Office reasons that the protease inhibitor disclosed in Caldwell is coated onto an absorbent article and the Office states that it would have obviously been in an amount greater than 0.0001% by weight and not greater than 30% by weight. Similarly, the Office goes on to list the additional limitations of Applicants' remaining claims that are rejected and points out certain portions of Caldwell that it believes discloses similar elements. The Office has withdrawn its previously filed rejection based on the obviousness of optimizing the range of protease inhibitor in the absorbent article and has based the current rejection on the obviousness of the absorbent article comprising the protease inhibitor in Applicants' claimed range. Applicants traverse this rejection.

Caldwell discloses barrier webs that have certain desirable physical qualities such as water resistance, increased durability, improved barrier qualities and the like. These barrier webs comprise webs that have been treated with a curable shear thinned thixotropic polymer composition, the fabric being adapted to be substantially impermeable to liquids, permeable to gases and impermeable to microorganisms. The barrier webs are either impermeable to all microorganisms or are impermeable to microorganisms of certain sizes. Despite the focus of the reference, it still fails to disclose the very elements that are being claimed currently.

Applicants respectfully submit that Claims 31, 32, 36, 41-46, and 48-53 are not obvious in view of Caldwell for a number of reasons. First, Caldwell does not teach or suggest Applicants' claimed concentration of protease inhibitors. Caldwell merely discloses

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that pentamidine is one of many antimicrobial agents suitable for inclusion into the claimed barrier web. The Office has failed to consider the full text of MPEP §2144.05 and the case law cited therein. The Office fails to point to a teaching within Caldwell that recognizes that the amount of pentamidine is a "results-effective variable" as required by *In re Antoine*, 195 USPQ 6, 8, 9 (CCPA 1977). Instead, the Office relies on Caldwell's disclosure of pentamidine in general as meeting Applicants' lower threshold of 0.0001% by weight and then the reference's mention of coating a surface as an implication of the fact that such a coating would not result in a protease inhibitor concentration of no more than 30% by weight. Applicants submit that this implied presumption is insufficient to render the present claims obvious since there is no express disclosure of the claimed range amount of pentamidine.

Second, Caldwell does not teach or suggest a protease inhibitor having an  $IC_{50}$  of about 500  $\mu$ M or less. The citation provided by the Office lists pentamidine as one of a large number of antimicrobials for use in the actual barrier web of Caldwell or as an ingredient for inclusion in a treatment on the web. No disclosure is contained within the reference with regard to  $IC_{50}$  values of any one of the antimicrobials listed therein. Thus, the Office has failed to teach or suggest all of Applicants' claim limitations.

The Office goes on to state that pentamidine inherently has "an  $IC_{50}$  of about 500  $\mu$ M or less, no more than 100  $\mu$ M, and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease." Such reasoning is misplaced since the doctrine of inherency has no place in the determination of obviousness. Caldwell fails to disclose or suggest that pentamidine is even a protease inhibitor and it surely does not teach or suggest the desirable  $IC_{50}$  values that are currently claimed as a function of the pentamidine. The Office has engaged in impermissible hindsight reconstruction since nothing other than Applicants' disclosure teaches or suggests the  $IC_{50}$  values.

Claims 32, 36, 41-47, and 48-53 depend from and contain all the limitations of Claim 31. Since Claim 31 is nonobvious in light of the arguments presented above, the claims dependent therefrom are also nonobvious for the same reasons.

### CONCLUSION

Based on the foregoing reasons, Applicants respectfully submit that the Office has not made a *prima facie* case of obviousness and the rejections are therefore improper. Reconsideration and withdrawal of the rejections are respectfully requested. Allowance of each of the pending claims in the next Office Action is respectfully requested.

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Respectfully Submitted,

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